

TOBACCO AND VAPING PRODUCTS



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Tobacco and vaping products: ANSES is publishing an unprecedented overview of products sold in France

Today ANSES is publishing its first assessment of tobacco and vaping products sold in France. The information provided on more than 3,000 tobacco products, mainly cigarettes, cigars and cigarillos, and more than 33,000 vaping products, primarily e-liquids packaged in refill containers or cartridges, was analysed. The analysis identified inconsistencies and non-conformities in the information reported, of which the manufacturers were informed to help them take appropriate corrective action. Based on this initial overview, ANSES is issuing recommendations to improve the reporting process throughout Europe. To date France is the first Member State to publish such detailed information on the products placed on the market under the new European regulations.

Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products came into force in May 2016. **Manufacturers of tobacco and vaping products have since been required to report on the composition, emissions, toxicity and sales volumes of their products before marketing them.** The Directive has also established a **specific regulatory framework for electronic cigarettes and e-liquids containing nicotine.** In France, ANSES has been designated to **collect and analyse all information from manufacturers,** and a roadmap has been drawn up for this purpose with the Directorate General for Health. The manufacturers must provide **comprehensive information** on ingredients in and emissions from tobacco products and products used with electronic cigarettes in order to **assess their attractiveness, addictiveness and toxicity,** and improve knowledge of the risks to human health associated with the consumption of such products.

The Agency carried out an unprecedented overview of the types and composition of products sold on the French market

The Agency reviewed the information submitted since May 2016. Between May 2019 and June 2020, **3 173 tobacco products and 33 813 vaping products** were reported to be sold on or intended for the French market. These were mainly cigarettes, cigars and cigarillos, as well as e-liquids packaged in refill containers or cartridges. This review enabled ANSES to draw up a list of reported substances found in the products. More than **850 additives were referenced for tobacco products,** while the first ever reference list for vaping products was drawn up, containing nearly **1,200 substances.**

The tobacco products reported for the French market contained a varying

number of additives. Cigars contained just one additive while an average of thirty were reported for cigarettes, and even more for pipe tobacco. The majority of additives were used as **flavour or taste enhancers**. These facilitate tobacco initiation by hiding its naturally acrid taste, and can also influence smoking habits. Under the European directive, manufacturers must provide in-depth studies on fifteen additives in cigarettes and roll-your-own tobacco, documenting their effects in terms of increased toxicity or addictiveness, increased nicotine inhalation and the forming of carcinogenic, mutagenic or reprotoxic substances. The studies submitted by manufacturers in mid-2018 are currently being evaluated by a group of European-level experts in particular.

Most **e-liquids for vaping** reported for the French market contained a diluting agent such as propylene glycol (PG) and/or glycerol (vegetable glycerine [VG]), had a mean nicotine content of approximately 6 mg/ml and could contain up to fifteen flavouring substances. The most common ones were derived from vanillin, maltol, menthol and esters with a fruity aroma. Sugars and sweeteners (e.g. glucose/fructose and sucralose), acids used in nicotine salts and plant extracts were also found.

This analysis enabled ANSES to identify inconsistencies and non-conformities and notify them to the reporting companies

Information on product composition and especially on sales volumes was **lacking**, and several **inconsistencies** in the information submitted were also apparent. On the basis of the information reported, some less frequent **non-conformities identified by the Agency included emissions above the regulatory threshold for certain cigarettes, and excessive nicotine content in some vaping products**. Rare cases were also identified involving the reporting of **prohibited substances**, such as vitamins and carcinogenic, mutagenic and reprotoxic substances.

ANSES informed all the reporting companies concerned of the non-conformities identified and **asked them to address the issues**, either by taking steps on the products or the information reported in accordance with the European process. **Non-compliant products require special attention** from the authorities to ensure that they are no longer offered for sale.

Drawing on its expertise, the **Agency will share its recommendations with the Commission and EU Member States to improve the reporting process**, especially as part of its contribution as a partner to the Joint Action on Tobacco Control (JATC).

This includes, for example, compiling a validated list of substances to avoid inconsistent information on ingredients or emissions being reported.

Data have been published to inform consumers

As part of its mission to inform the public, ANSES is publishing the list of reported products, along with their characteristics and composition, and any discrepancies identified in the information submitted, on its website (tobacco data, vaping data) and on data.gouv.fr.

To date France is the first Member State to publish such detailed information on the products placed on the market.

Beyond regulatory compliance requirements, the current concern is the assessment of health risks associated with inhaling certain chemicals contained in vaping products and new heated tobacco products.

Work on ranking the substances in question is under way as this is a prerequisite for any risk assessment process.

WHAT IS MEANT BY TOBACCO AND VAPING PRODUCTS ?



Tobacco products consist fully or partly of tobacco. They include **cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco (snuff) and new heated tobacco products.**

Vaping products are electronic “vaping” devices, i.e. products – or any component thereof, including cartridges and tanks and devices without cartridges or tanks – that can be used via a mouthpiece **for the consumption of vapour containing nicotine.**

Electronic vaping devices, more commonly known as **e-cigarettes** may be disposable or refillable.

An e-cigarette usually consists of **three main parts: an atomiser, an e-liquid cartridge and a battery.**

Vaping products also include **refill containers**, i.e. receptacles holding a liquid that may contain nicotine. As the name suggests, refill containers are **used to refill an electronic vaping device.**

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REPORTING ON PRODUCT COMPOSITION : AN OBLIGATION FOR MANUFACTURERS AND A SOURCE OF DATA FOR ANSES

Since the entry into force of **Directive 2014/40/EU** on the manufacture, presentation and sale of tobacco and related products, **such products must be registered before they are marketed.**

Under the directive implemented in all Member States of the European Union since **20 May 2016** :

- **Manufacturers must submit information** on product composition, ingredient toxicity and sales data, among other things.
- **A specific regulatory framework for electronic cigarettes and e-liquids containing nicotine has been established.** Under this framework, manufacturers and importers are required to submit information on the characteristics, composition and emissions of products to the competent authorities six months before placing the products on the European market.

This reported information is critical for the government to better understand the composition of products and their impact on consumer health depending on how they are used, and monitor changes in supply and demand.

In 2016 ANSES was tasked with **collecting and analysing all the data submitted by manufacturers** in support of the Ministry of Solidarity and Health.

France is the first Member State to publish such detailed information on the products placed on the market

To date France is the first Member State to **publish such detailed information** on the products placed on the market (e.g. a list, characteristics, composition and inconsistencies identified in the notification files) under the new European regulations.

For cigarettes and roll-your-own tobacco

Limites d'émissions par cigarette :

- 10 mg of tar
- 1 mg of nicotine
- 10 mg of carbon monoxide



Packaging

- 20 cigarettes minimum per pack
- 30 g minimum of roll-your-own tobacco per pouch

Prohibited additives :

- *Substances classified as carcinogenic, mutagenic or reprotoxic (CMR)
- *Vitamins and other substances with health benefits
- Caffeine, taurine and substances with a stimulant effect
- Substances that impart a clearly perceptible aroma different from tobacco
- *Smoke dyes, products facilitating nicotine absorption, etc.

Traceability and safety:

- A unique identifier is used to track the product from the place of manufacture to the point of sale.
- Packs are authenticated through visible and invisible safety methods.

Labelling :



- Visible health warnings and shock images (in addition to neutral packaging in France)



Any statement, device or other means used to :

- suggest the minimisation of health risks,
- refer to a particular taste or smell or the presence/absence of additives,
- make the product look like a cosmetic or food product,
- suggest environmental benefits or offer commercial advantages is prohibited.

For vaping products

E-liquid refill container :

- Nicotine content: less of equal to 20 mg/mL (consumer product subject to registration)
- Volume up to 10 mL
- Cap with child safety device



Prohibited additives :

- Same prohibited additives as for cigarettes and roll-your-own tobacco (except those imparting a flavour)

The instruction leaflet, must include :

- Instructions for use
- Contra-indications
- Adverse effects

Labelling :



- The warning “*The nicotine contained in this product is highly addictive. Its use by non-smokers is not recommended.*”
- List of ingredients
- Nicotine content
- Batch number



- Contribute to the product's promotion or advertising
- Resemble a food or cosmetic product
- Improve the product's image

3 THE AGENCY HAS CARRIED OUT AN UNPRECEDENTED OVERVIEW OF THE PRODUCTS SOLD ON THE FRENCH MARKET

As part of this new task, ANSES is publishing a list of products sold on the

French market, as well as data on identified substances, and ingredients and additives used in product composition, among other information.

Based on the information reported by manufacturers, the Agency carried out an assessment of reported products in two separate reports, one on tobacco products and the other on vaping products.

The information submitted is collected by the European Commission via a centralised system.

ANSES conducted substantial methodological work, which included developing a database to organise and analyse the large volume of information obtained through the system.

It also reviewed the information submitted since May 2016. Between May 2019 and June 2020, **3 173 tobacco products and 33 813 vaping products** were reported to be sold on or intended for the French market.

Tobacco products mainly included cigarettes, cigars and cigarillos, as well as waterpipe tobacco. The majority of vaping products were e-liquids packaged in refill containers or cartridges.

3 173 tobacco products and 33 813 vaping products reported

Tobacco products

- ▶ **3,173 products analysed, including:**
 - 41.5% cigarettes
 - 35.5% cigars and cigarillos
 - 9.7% waterpipe tobacco
 - 5.3% roll-your-own tobacco
- ▶ **Around 85 reporting manufacturers and importers**
- ▶ **Around 850 identified additives in the products**
- ▶ **Just under 50 new products notified and one to three new reporting companies entering the market each month**
- ▶ **Half the information submitted was reported by the 4 leading international tobacco companies in Europe, and one quarter by cigar importers and manufacturers.**

The tobacco products reported contained a **varying number of additives**. Cigars contained **just one additive while an average of thirty was reported for cigarettes**, and even more for pipe tobacco. **The majority of additives were used as flavour or taste enhancers**, such as menthol used in nearly 20% of cigarette references*, and plant extracts.

Under the European directive, manufacturers must provide in-depth studies on fifteen additives in cigarettes and roll-your-own tobacco, documenting their effects in terms of increased toxicity or addictiveness,

increased nicotine inhalation and the forming of carcinogenic, mutagenic or reprotoxic substances. The few studies submitted by manufacturers in mid-2018 are currently being evaluated by a group of European-level experts in particular.

Tobacco smoke contains more than 7,000 chemicals, at least 70 of which are known to cause cancer. Nicotine is the addictive substance in tobacco.

*Since 20 May 2020, the sale of menthol-flavoured cigarettes and roll-your-own tobacco has been banned in France and throughout the European Union, as provided for by the European directive. The impact of this ban was not observable on the 2019–2020 assessment.

Vaping products

- ▶ **33,813 vaping products** analysed, 78.8% of which were e-liquids packaged in refill containers or cartridges
- ▶ **Around 700 reporting manufacturers and importers**
- ▶ **Nearly 1,200 substances used in ingredients and more than 600 found in emissions**
- ▶ **500 new products notified** on average and ten or so new manufacturers entering the market each month
- ▶ **80% of reporting companies** mainly for e-liquids, **three-quarters of which were produced by French or European manufacturers**

Most e-liquids for vaping reported for the French market:

- contained a **dilution agent** such as propylene glycol (PG) and/or glycerol (vegetableglycerine [VG]);
- had a **mean nicotine content of approximately 6 mg/ml**;
- contained **up to 15 flavouring substances and additives**. The most common ones were derived from **vanillin, maltol, menthol and esters with a fruity aroma**. Sugars and sweeteners (e.g. glucose/fructose and sucralose), acids used in nicotine salts and plant extracts were also found.

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THE AGENCY PUBLISHES A LIST OF REPORTED PRODUCTS ALONG WITH THEIR COMPOSITION AND AN INDICATION OF THE QUALITY AND COMPLIANCE OF SUBMITTED DATA

The assessment generally highlighted a **quality issue with the data submitted by manufacturers**. Information on product composition, and more often on sales volumes was lacking, and several inconsistencies in the information submitted were also apparent.

Moreover, with regard to vaping, there were **uncertainties about the proportion of products consumed that were not notified**. This is because nicotine-free products, and those made by the consumer (DIY vape liquid), are not required to be notified.

Some less frequent **non-conformities identified by the Agency** included emissions above the regulatory threshold for certain cigarettes, and excessive nicotine content in some vaping products. **Several prohibited additives**, such as vitamin C and **carcinogenic, mutagenic and reprotoxic** substances were also identified.

Drawing on the information reported by manufacturers, **ANSES was able to improve understanding of product composition**, thereby facilitating the future monitoring of market trends.

As part of its mission to inform the public, ANSES is **publishing on its website** ([tobacco data](#), [vaping data](#)) and on [data.gouv.fr](#) the list of reported

The assessment generally highlighted a quality issue with the data submitted by manufacturers.

products, along with their characteristics and composition, and **any discrepancies identified in the information submitted**.

This information will be updated regularly. At the same time, the Agency has planned to conduct sampling campaigns and analyses of products available on the market, which will supplement the review of reported information and provide input for expert appraisal work.

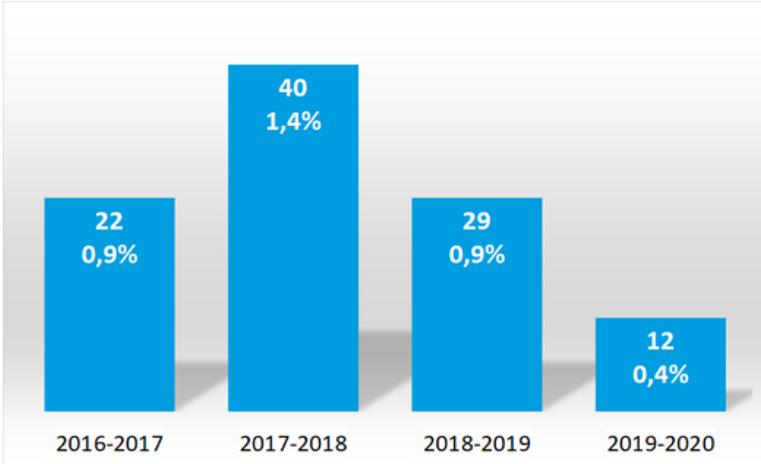
The Agency has flagged up inconsistencies and non-conformities in the information reported and is asking manufacturers to address the issues highlighted.

Drawing on its expertise, the Agency will share its recommendations with the Commission and EU Member States to improve the reporting process, especially as part of its contribution as a partner to the Joint Action on Tobacco Control (JATC). This includes, for example, compiling a validated list of substances to avoid inconsistent information being reported on ingredients or emissions.

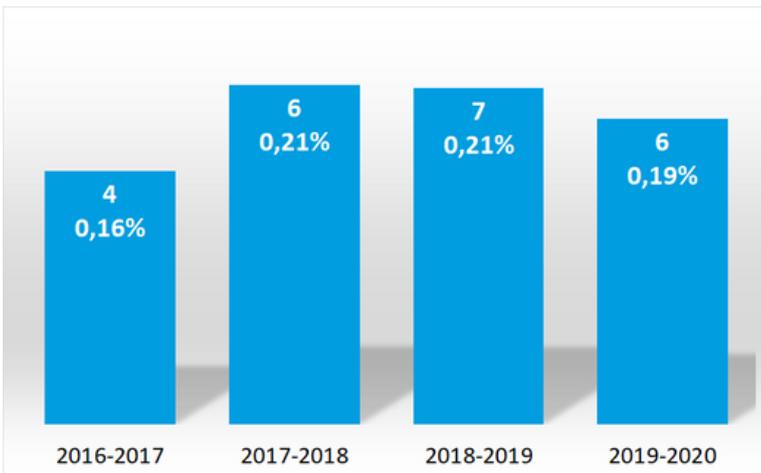
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Tobacco – non-conformities for reported products

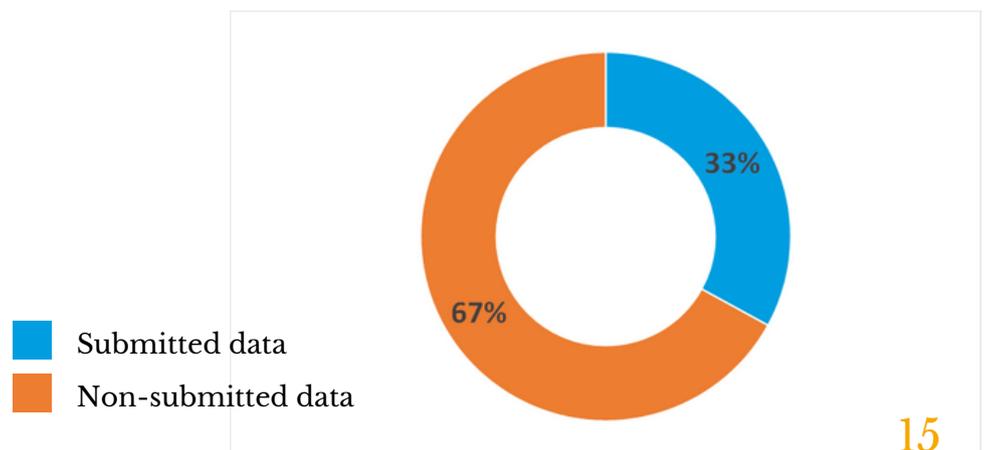
Proportion of tobacco products reported to be on the market with at least one CMR (carcinogenic, mutagenic and reprotoxic) ingredient



Proportion of tobacco products reported to be on the market with at least one prohibited ingredient (vitamins, caffeine, or taurine)

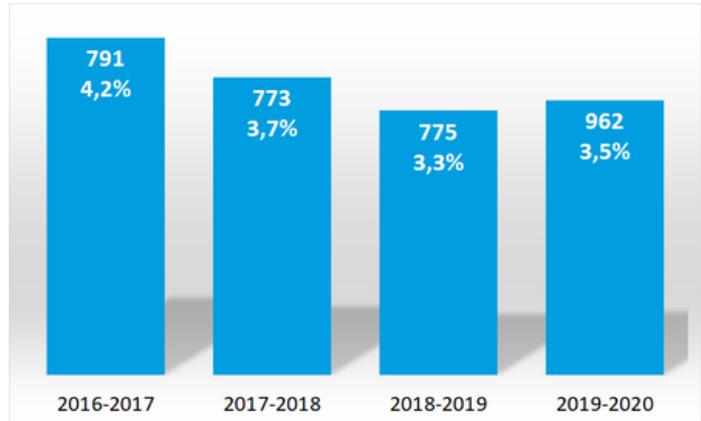


Submission of sales data (tobacco products reported to have been on the market between 2016 and 2020)



Vaping – non-conformities for reported products

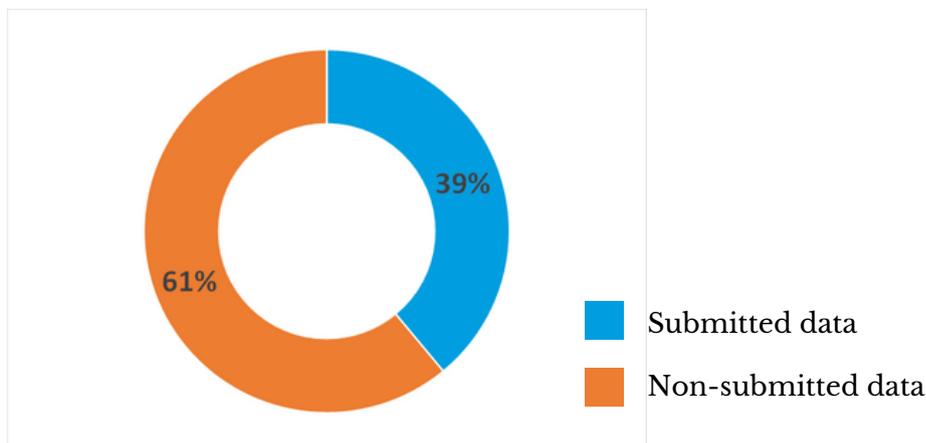
Proportion of vaping products reported to be on the market with at least one CMR (carcinogenic, mutagenic and reprotoxic) ingredient



Proportion of vaping products reported to be on the market with at least one prohibited ingredient (vitamins, caffeine, or taurine)



Submission of sales data (tobacco products reported to have been on the market between 2016 and 2020)



5 FOCUS ON VAPING

Improving knowledge of products, the market and consumer practices and reviewing cases of poisoning to assess potential risks

The adverse health effects of smoking are now widely known and documented. **The challenge now is to assess the health impact of consuming vaping products.** Specifically, the risks could be caused by **inhaling certain additives or substances formed from the interaction of these ingredients** during consumption, generated during heating or transferred by the electronic device, for example. To conduct this risk assessment, ANSES has initiated work to **rank the substances according to the potential risk of inhaling them and estimate exposure through different consumption practices.**

As part of this work, the Agency has already **coordinated and funded three studies** to better understand this booming market, the range of players involved in what is a complex landscape and the various consumption routes, as well as the reported cases of poisoning:

- **A study on manufacturers:** mapping of market players and their positioning
- **A study on the practices of French vapers:** BVA survey
- **A study on accidental poisoning reports:** toxicovigilance mission in collaboration with poison control centres

Mapping of market players and controversies

The vaping market is made up of a large number of different types of companies marketing the products: contract manufacturers*, small-scale makers, large distributors and kit producers. In contrast to the standardised cigarette market with its exclusive sales channels, highly regulated products, government-controlled prices and packaging, and because of the wide range of players involved, the e-liquid market shows a great deal of creativity (with the product itself covering low- to high-end segments, the ancillary advice and services offered and accompanying sales pitches).

The study revealed the **key influence of the regulatory framework on the companies' positioning**. This is a **promotional argument** for contract manufacturers, is widely used in debating the health aspects of vaping versus smoking, and leads, in perhaps a more roundabout way, to explicit adaptive behaviours of circumvention through the separate sale of concentrated nicotine (so-called boosters) and many other components.

Such separate offers **encourage artisanal DIY practices** among consumers, who can get the equipment required for dosing, mixing and formulating their own product composition from the companies on the market.

Lastly, the study highlights the **empowerment of the vaping community compared to the community of smokers and users of pharmaceuticals**: vaping is neither just another way of smoking, nor an aid for stopping smoking.

More than four years after the establishment of the European regulatory framework, **key questions about the products' toxicity, long-term effects, effectiveness in helping people stop smoking and gateway effect to smoking have remained largely the same**. For most companies marketing the products, health issues are a minor argument, and they prefer to focus on the products' safety according to industrial standards. Health claims are only emphasised by companies actively campaigning for a harm reduction policy for smokers.

*Contract manufacturers are companies that follow a model similar to IT equipment manufacturers, by offering a range of associated services, including brand management.

Study on consumer practices

At the request of ANSES, in February 2020 the BVA polling institute conducted an online **survey on e-cigarette use** among a representative sample of 1,000 daily or occasional vapers aged 18 to 75.

The objective was to collect detailed information at source on **consumer habits** as well as technical details on the **products and devices used**. This survey was part of a **wider approach to understand consumer habits and exposure to tobacco and related products**. It is expected to be updated regularly by similar studies.

Information on smoking status, materials used, product composition and consumer preferences confirmed the data reported by the European industry or acquired through other surveys. The results also provide **original information on consumer practices such as DIY vape making, where and when vapers vape**, their use of equipment features, and how much they know about the composition of the products consumed.

Amongst the vapers surveyed:

- **Three out of four vaped daily.**
- Sixty-three percent of vapers were also smokers and **37% were not also smokers**, and amongst these, 34% were former smokers and 3% said that they had never smoked or only once to try.
- The majority of vapers had been using e-cigarettes for 2 years or more (58%).

Le sondage apporte des informations inédites sur les pratiques de consommation

- Among the main reasons cited by vapers for using e-cigarettes, **68% said that vaping was a way of stopping smoking**, 36% said that **vaping was cheaper than smoking regular cigarettes** and 30% thought that e-cigarettes were a healthier option.
- **Seventy percent of vapers thought that e-cigarettes were less harmful than tobacco.**
- “Fruit” and “tobacco” flavours were the most popular and 49% used more than one flavour.

The study also confirmed the use of nicotine-free products, which are not covered by reporting obligations. **Thirty-five percent of the vapers surveyed used nicotine-free products**, and this was an exclusive use for 21% of them. The results also highlighted the **importance of DIY making, since 40% of vapers said that they made their own e-liquid**. For two-thirds of them, this was for cost reasons.

Study on accidental poisoning cases

Since their introduction, e-cigarettes have stimulated scientific and societal debate about the risks associated with their use and potential benefits in helping people cut down smoking. Possible risks are related to chemical substances potentially emitted during vaping and which may be inhaled by the consumer or by people around them. These are substances that are added as e-liquid ingredients, generated through heating or transferred by the electronic device, for example.

Beyond the long-term effects that several epidemiological and experimental studies have begun to investigate around the world, there is the **issue of effects through accidental exposure.**

ANSES has established a partnership with poison control centres **to monitor reports of acute poisoning cases due to vaping.** An initial study based on poison control centres was published in 2017: [*Do electronic cigarettes cause serious accidents?**](#)

A second study was initiated in July 2019 and will be completed by the end of 2020. **Preliminary results are reassuring** and show no deaths or lung illness similar to the American outbreak at the end of 2019.

Moreover, **10 to 20% of accidental exposure cases were caused by DIY vape making.** Lastly, most cases resulted from misuse by other people in vapers' homes.

No deaths or lung illness similar to the American outbreak at the end of 2019

*To read the whole study: http://www.centres-antipoison.net/CCTV/CCTV_Rapport_Cigarettes_electroniques_VFINALE.PDF



OUTLOOK FOR THE AGENCY'S WORK

In order to verify the accuracy of reported data and the steps taken by manufacturers to correct non-conformities or inconsistencies, **ANSES will soon carry out analytical work on a sample of products on the market to compare findings with the information reported.**

Beyond regulatory compliance requirements, **the current concern is the assessment of health risks associated with inhaling certain chemicals contained in vaping products and new heated tobacco products.**

First, ANSES has already **begun the ranking process of substances to be assessed** using:

- inhalation hazard criteria,
- estimated exposure through different vaping practices.

To do this, **ANSES will coordinate new surveys** to improve knowledge of consumer profiles against the changing context of consumer products and habits.

The Agency will then be able to carry out **targeted assessments of risks** according to the substances contained in the products that are found to be of greater concern for the health of consumers.

The current concern is the assessment of health risks associated with inhaling certain chemicals contained

Tobacco and vaping products: an overview of the Agency's role

- **Informing the public on products sold in France:** ANSES publishes and regularly updates a list of registered products on the market, along with their composition and discrepancies identified in reported information.
- **Providing scientific and technical support to the authorities:** ANSES is providing essential information to help the authorities enforce the regulations and monitor product compliance, including market changes, product composition and future additional assessments and analyses of marketed products.
- **Assessing the risks associated with vaping products and heated tobacco:** characterising chemical substances and updating studies on practices in France to estimate exposure and health risks caused by inhaling these substances.
- **ANSES is also involved in the [Joint Action on Tobacco Control \(JATC\)](#)** project funded at European level to support implementation of the Tobacco Products Directive by the Member States. The Agency is participating in various project tasks, including on the analysis of toxicological data for ingredients and additives in tobacco and vaping products.



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